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09/929,565	08/14/2001	Jean-Francois Barault	ETH1475	9842

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EXAMINER
PANTUCK, BRADFORD C

ART UNIT	PAPER NUMBER
3731	8

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/929,565	Applicant(s) BARAULT, JEAN-FRANCOIS
	Examiner Bradford C Pantuck	Art Unit 3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *02 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *1-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3 & 6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Amended Claim 15 recites the limitation "the reinforcing element" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 13, 14, 18, 22, 24, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,497,650 to Nicolo. Regarding independent Claim 18, Nicolo discloses a mesh-like implant, according to the claimed invention. Nicolo's implant (12) is made out of mesh [Column 4, lines 16-18; Fig. 2a], and has a reinforced zone (14) in a central area of the implant and a peripheral area. Figure 4 shows the implant, and the reinforced zone (14), which extends from the central part of the implant to a peripheral part of the implant. The reinforced zone has a smaller

pore size on average than the peripheral area. The reinforced zone is composed of two layers—a layer of the material that composes the implant in general (12) and a layer of reinforcing material (14) that has a very small pore size. The pore size of the mesh reinforcing material (14) is very small ["submicronal"] so as to prevent body tissue from penetrating the pores and growing into the mesh [Column 4, lines 45-53].

3. Regarding Claim 22, Nicolo discloses a mesh-like implant that can be weft-knitted or warp-knitted. Describing his mesh fabric prosthesis, in Column 4, lines 38-42, Nicolo says that "woven, molded and other *suitable methods of forming prosthetic mesh materials* may be employed." It is well known in the art of making surgical mesh that weft knitting and warp knitting are common ways of making surgical mesh, as demonstrated by U.S. Patent No. 6,391,060 to Ory [Column 3, lines 50-59].

4. Regarding Claim 24, Nicolo discloses an implant, in which the reinforced zone is made by attaching a first weft-knitted or warp-knitted mesh to a second weft-knitted or warp-knitted mesh, and the peripheral area of the implant is that portion of the second mesh that is not covered by the first mesh. The reinforced zone [the area covered by and including the first mesh (14)] can be warp or weft-knitted, as explained above with reference to Claim 22. The two meshes are attached to each other [Column 6, lines 20-28].

5. Regarding Claim 25, Nicolo discloses the invention, as claimed. Reinforcing element (14) overlying mesh (12) can be said to reinforce the central part of the prosthesis as well as reinforcing the prosthesis radially, as the reinforced area spreads from the center of the implant to its outer edge [see Fig.2a].

6. Regarding Claim 13, Nicolo discloses an implant made out of resorbable material [Column 4, lines 35-39, and 63-65]. To "resorb" and to "absorb" mean essentially the same thing: to dissolve and assimilate.

7. Regarding Claim 14, the resorbable material of Nicolo can be a copolymer of lactide and glycolide, otherwise known as VICRYL [Column 4, lines 35-39].

8. Claims 18-22 are also rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,391,060 to Ory et al. Regarding Claims 18 and 19, Ory discloses a mesh-like implant (1) with a mesh-like basic structure (1a) and a homogenous reinforced zone (inside of red line in below Fig. 4) in a central area of the basic structure. The strength of the said reinforced zone decreases towards the peripheral area. Clearly, the reinforced zone will be stronger than the peripheral area of the basic structure, as there is an extra layer of mesh in the reinforced zone (as shown in Fig. 4 below). The reinforced zone (inside red lines) has a homogenous central area (colored yellow in Fig. 4) and a zone (area between red line and outer edge of panel 9) of lower strength surrounding the homogenous central area.

[SOURCE: U.S. Patent No. 6,391,060 B1 to Ory et al.]

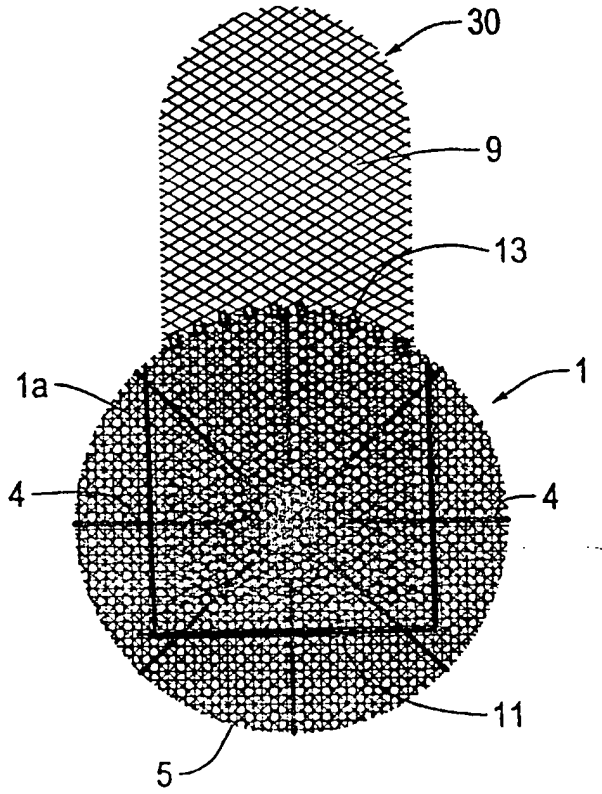


Fig. 4

9. Further regarding Claim 18, Ory's reinforced zone (inside of red lines in above Fig. 4) is made out of mesh and will have a smaller pore size than the peripheral area of the basic structure (1a). The homogenous central area (yellow in Fig. 4) in the reinforced zone of Ory's implant (1) consists of one mesh laid on top of another piece of mesh [Column 5, lines 5-17]. When adding a sheet of fabric on top of another sheet of fabric, inevitably the fibers of the two fabrics will not line up perfectly, i.e. some of the fibers of the upper fabric will be located above the pores (interstices) of the fabric below, or vice versa. In other words, the pore size will be decreased by the addition of a second sheet of mesh. Therefore, the reinforced zone in Ory's mesh will have a smaller pore size than the peripheral area of the basic structure.

10. Regarding Claim 20, Ory discloses an implant, containing all of the limitations of Claim 18, in which radial reinforcing elements (4) extend from the reinforced zone *to the peripheral edge* of the basic structure (1a) [see Fig. 4].

11. With respect to Claim 21, Ory shows an implant according to the applicant's invention, including at least one radial reinforcing element (4) that is widened in the area of the peripheral edge (5) of the basic structure (1a). The radial reinforcing elements and the discontinuous overstitching (8), as divulged by Ory, are made out of the *same thread* and therefore the overstitching is merely an extension—a widened area—of each radial element [Column 4, lines 17-20 and lines 54-58]. Because the radial reinforcing elements *intersect* the overstitching (8) and the two are made from an identical substance, one would say that the overstitching (8) is merely a widened area of each radial reinforcing element.

12. Regarding Claim 22, Ory discloses an implant with a weft-knitted or a warp-knitted basic structure [Column 3, lines 50-59].

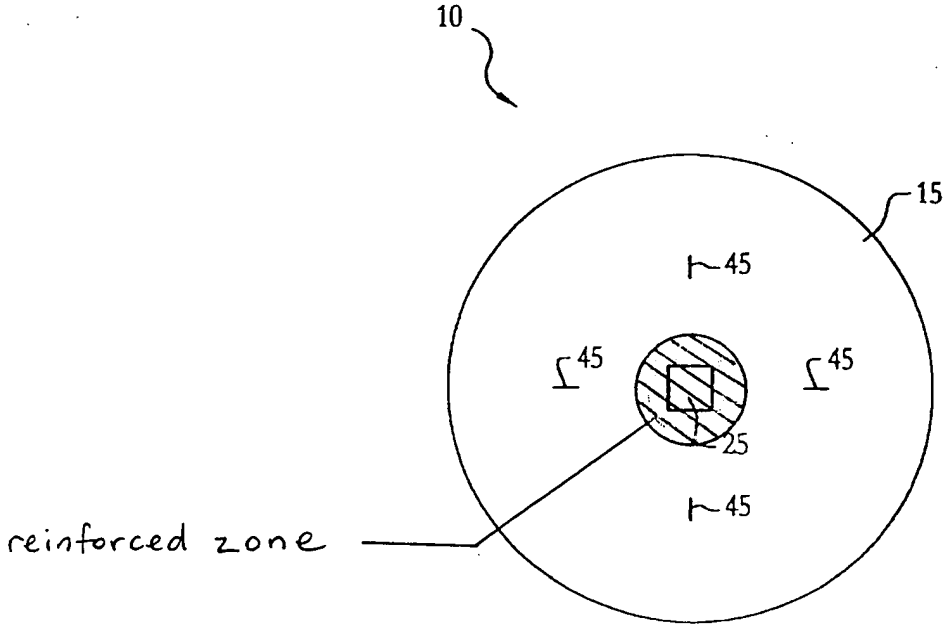
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

13. Claims 18, 19, 22, and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent No. 6,066,776 to Goodwin et al. Regarding Claims 18 and 19, Goodwin discloses an areal implant (10) with a mesh-like basic structure (15) and a reinforced zone (labeled in FIG. 2 below) in a central area of the basic structure. The strength of the said reinforced zone decreases towards the peripheral area. Clearly,

the reinforced zone will be stronger than the peripheral area of the basic structure, as there is an extra layer of mesh in the reinforced zone [Column 3, lines 41-46]. The reinforced zone (black diagonal lines in FIG. 2 below) has a homogenous central area (25) and a zone (yellow area in FIG. 2 below) of lower strength surrounding the homogenous central area.

FIG. 2

[SOURCE: US. Patent No. 6,066,776. to Goodwin et. al.]



14. Further regarding Claim 18, Goodwin's reinforced zone (black stripes in FIG. 2 above) is made out of mesh and will have a smaller pore size than the peripheral area of the basic structure (15). The homogenous central area (25) in the reinforced zone of Goodwin's implant (10) consists of one mesh laid on top of another piece of mesh [Column 3, lines 41 to 48]. When adding a sheet of fabric on top of another sheet of fabric, inevitably the fibers of the two fabrics will not line up perfectly, i.e. some of the fibers of the upper fabric will be located above the pores (interstices) of the fabric below, or vice versa. In other words, the pore size will be decreased by the addition

of a second sheet of mesh. Therefore, the reinforced zone in Goodwin's mesh will have a smaller pore size than the peripheral area of the basic structure.

15. Regarding Claim 22, Goodwin discloses an implant *knitted out of surgical mesh* [Column 3, lines 23-28 in view of *Instructions for Use* by Atrium Medical Corporation, included] with a weft-knitted or a warp-knitted basic structure. It is well known in the art of making surgical mesh that weft knitting and warp knitting are common ways of making surgical mesh.

16. Regarding Claim 23, Goodwin discloses the claimed invention except the various components of Goodwin's implant are weft-knitted or warp-knitted *separately*, and then *combined* to form one piece. It would have been obvious to one having ordinary skill in the art at the time the invention was made to knit the implant [including the basic structure, the reinforced zone and the homogenous central area] in one piece rather than knitting each part separately and combining them, since it has been held that constructing a formerly piecemeal structure in integral form involves only routine skill in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,066,776 to Goodwin et al., in view of U.S. Patent No. 6,162,962 to Hinsch. Regarding Claims 13 and 14, Goodwin discloses a mesh-like implant with a reinforced zone in the middle made out of one of a number of non-resorbable materials. Goodwin does not disclose an implant made out of a specifically resorbable material, as specified in Claims 13 and 14, although Goodwin explains that his implant can be made out of any biomaterial suitable for surgical applications [Column 3, lines 23-32]. One requisite for these biomaterials, as recited by Goodwin, is that they promote tissue ingrowth and attachment to surrounding tissues [Column 3, lines 37-40]. Hinsch discloses an areal implant made out of resorbable materials [Column 11, Claim 8], including poly-p-dioxanone and lactide/glycolide copolymers [Column 11-12, Claim 12].

These resorbable materials are used, as recited by Hinsch, so that the implant will be resorbed by and attach to the tissues around it. Therefore, one would use Hinsch's resorbable materials to facilitate tissue ingrowth in Goodwin's implant. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the specific resorbable materials, as taught by Hinsch, for the non-resorbable materials of Goodwin's implant for the purpose of making the implant be more easily assimilated into the body tissues.

18. Regarding Claims 15-17, Goodwin shows all of the claimed limitations except for the film that is used as a stiffening element in the applicant's implant. The mesh of Goodwin's implant, although it lacks the stiffening film, is meant to promote tissue

ingrowth in addition to being of a "sufficient strength and integrity" [Column 3, lines 33-39]. Hinsch teaches that it is known that one can apply a resorbable "stiffening material" such as a "film" to an implant [Column 3, lines 35-40] in order to cause the implant to be more firm as well as for purpose of facilitating tissue ingrowth [Column 2, lines 55-63]. *A stiffening element can also be called a reinforcing element.* The film is located on the peripheral area of the implant. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply Hinsch's resorbable film as a coating for Goodwin's implant in order to strengthen the implant and to better facilitate tissue ingrowth.

Response to Arguments

19. Applicant's arguments filed April 2, 2003 have been fully considered but they are not persuasive. Regarding the Applicant's contention that Goodwin and Ory fail to disclose a reinforced zone with a smaller pore size than the mesh of the peripheral area, the Examiner maintains his rejection. The overlapping meshes in the central reinforced zones of Goodwin and Ory will combine to produce a net [sum] effect of a fabric with smaller interstices. There is no motivation shown in either reference for exactly aligning the fibers of each mesh, so it must, therefore, be assumed that the pores [interstices] of the meshes will interfere to some degree. Finally, U.S. Patent No. 6,497,650 to Nicolo [published since the First Office Action] incontrovertibly discloses a mesh-like implant with a reinforced central zone with a smaller pore size than the peripheral area.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,254,133 to Seid.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

BCP
BCP
May 2, 2003

MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700